Kansas Medical Assistance

DRUG UTILIZATION REVIEW BOARD

Meeting Minutes, Open Session

January 14, 2004

DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session KAW Area Technical School, Basement Testing Center Topeka, Kansas January 14, 2004	**Members Present:** R. Kevin Bryant, M.D., CMD; Linda Kroeger, ARNP; John Lowdermilk, R.Ph.; Barry Sarvis, R.Ph.; Brenda Schewe, M.D.; Kevin Waite, PharmD; John Whitehead, D.O. **SRS Staff Present:** Nialson Lee, B.S.N, M.H.A.; Mary Obley, R.Ph.; Vicki Schmidt, R.Ph., DUR Program Director; Erica Miller **EDS Staff Present:** Karen Kluczykowski, R.Ph.	**Representatives:** Gary Pedersen (Bayer), Mike Huffles (Ks Governmental Consulting), Jim Baumann, R. Ph (Pfizer), Bruce Steinberg (Aventis), Marc Ontell (Sepracor), James Lieurance (Takeda), Kathleen Carmody (Lilly), Craig Boon (Heritage Information Systems, Inc.), Dr. Thomas Roth (Henry Ford Hospital, Director of Sleep Center), Diana Morasch (AstraZeneca), Susan Zalenski (Sanofi-Synthelabo), Josh Lang (Novartis), Carol Curtis (AstraZeneca), Jeff Knappen (Allergan), Lon Lowrey (Novartis), Patty Laster (Genentech, Inc), Danny Ottosen (Berteck Pharmaceuticals)

TOPIC	DISCUSSION	DECISION/ACTION
I. Call to Order	• Dr. Brenda Schewe, Acting Chair, called the Open Meeting of the Drug Utilization Review Board to order at 9:45a.m.	
II. Review and Approval of November 12, 2003, Meeting Minutes	• There were no additions or corrections to the November 2003 meeting minutes.	• A motion to approve the minutes as written was made by Mr. Sarvis and seconded by Dr. Waite. The motion carried unanimously by roll call.

III. Old Business **A. Review Prior Authorization Criteria for Ambien/Sonata**	• Dr. Schewe reminded everyone that they talked about this at the last meeting. • Vicki pointed out that SRS was asked to bring Ambien and Sonata back with limits.	
TOPIC	**DISCUSSION**	**DECISION/ACTION**
Public Comment **DUR Board Discussion**	• Dr. Thomas Roth (Henry Ford Hospital) is the Director of the Sleep Center. Dr. Roth stated that he has two concerns with adding limitations to Ambien and Sonata. First is the nature of the insomnia. Insomnia can be a chronic disorder, 80% of insomniacs will continue to have insomnia one year later. On average 14% use drugs to help them sleep every night. National Institutes of Health (NIH) says that they plan to revisit this class of drugs. According to the manufacturer's label it is permissible to take Ambien or Sonata for 30-35 days. • Dr. Bryant stated that with a hard edit there would be no further form to bypass the hard edit. Mary agreed. • Dr. Schewe pointed out that we haven't done anything before with Ambien and Sonata because benzodiazipines were not covered at the time. • Dr. Schewe stated that the Ambien and Sonata hard edits would not go into effect until Benzodiazapines are covered. • Dr. Whitehead stated that he would be more in favor of having a prior authorization instead of a hard edit, so the beneficiaries that need Ambien or Sonata for longer periods of time can get it. • Vicki asked if they would prefer SRS to do an	

	edit with a prior authorization that could override the edit. • Dr. Whitehead stated that he would be in favor of an edit with a prior authorization. He also pointed out that if they don't use Ambien or Sonata they will use something else. • Vicki asked Dr. Roth when the NIH will review	
TOPIC	**DISCUSSION**	**DECISION/ACTION**
DUR Board Recommendation	• Ambien and Sonata. Dr. Roth answered the last quarter of 2004 or first quarter of 2005. He also pointed out that just because they are reviewing Ambien and Sonata again it does not mean they will be changing their recommendations. • With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Whitehead and seconded by Mrs. Kroger to amend the SRS recommendation to allow a quantity of 31 per month for Ambien - 5mg & 10mg and allow 31 per month for Sonata 5mg and 62 per month for Sonata 10mg as an edit with no allowance for a prior authorization. The edit will not become effective until the benzodiazepines are covered. The motion carried unanimously by roll call.
V. New Business **A. Xolair** **Discussion of Prior Authorization Criteria**	• Dr. Schewe asked if the specialist needed to be by name or board certification. • Vicki answered that it would need to be a	

Public Comment	specialist by name. • Dr. Schewe pointed out that the patient must meet all criteria on prior authorization. • Josh Lang (Novartis) pointed out that the prior authorization form is not in complete agreement with the Xolair label. On the body weight chart 90-150kg/30-100 IU/mL should have a dose of 300mg, 70-90kg/300-400 IU/mL should have a dose of 300mg. Mr. Lang thinks that question 9 should be spilt into 2 sections 4 weeks and 2 weeks. He also thinks that question 10 is slightly confusing because usually allergic asthmatics have other allergies, Mr. Lang requests that we leave the question, but tell the physician that the patient will not be denied if they have other	
TOPIC	**DISCUSSION**	**DECISION/ACTION**

Xolair - Continued	allergies. On question 11, this should be listed as physician, since the physician administers the injection and then has to observe the patient for a short period of time following the injection. Question 1, should include moderate asthmatics. The FDA has approved Xolair for moderate and severe asthmatics. If moderate asthmatics are added, question 8 should also include baseline FEV1 and PEF needs to be ≤ 80%.	
DUR Board Discussion	• Dr. Whitehead asked if a pulmonologist, allergist, or immunologist reviewed the criteria. • Vicki stated that we have not had a specialist review this, but when you include the changes Josh Lang stated this is what the manufacturer recommends. • Mr. Sarvis asked if anyone has prescribed Xolair and if there are any pharmacies in Kansas that can supply Xolair. • Vicki stated that she believes we have two beneficiaries receiving Xolair. There are currently no pharmacies in Kansas that can supply Xolair. • Dr. Waite pointed out that a pharmacy cannot keep Xolair in stock unless they have the beneficiaries name that is receiving Xolair.	
DUR Board Recommendation	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Whitehead and seconded by Dr. Bryant to amend the SRS recommended criteria to: **1.** Moderate or severe asthma diagnosis. **2**. Severe persistent asthma diagnosis for, ≥ to 1 year. **3**. Daily medications and dose prescribed for the treatment of this diagnosis.
TOPIC	**DISCUSSION**	**DECISION/ACTION**

Xolair - Continued

Approved therapies: Inhaled Corticosteriod (Qvar, Beclovent, Venceril, Venceril DS, Pulmicort Turbuhaler, AeroBID, AeroBID M, Flovent, Azmacort)
AND one of the following: Long Acting b2 agonist **AND/OR** Leukotriene modifier (Singulair, Accolate, Zyflo) **AND/OR** Theophylline **AND/OR** Oral Corticosteriod recommended for uncontrolled asthma (prednisone, medrol, hydrocortisone, dexamethasone)

4. A spacer for inhaled medications must be prescribed. **5**. Symptoms persist despite patient being compliant with daily medication for a minimum of 6 months prior to request. **6**. Limited physical activity. **7**. Frequency of exacerbation needs to be 2 week; frequency of nightly symptoms needs to be 1per week. **8**. Forced Expiratory Volume in one second (FEV1) or Peak Expiratory Flow Rate (PEF) needs to be ≤ to 80%, PE variability needs to be ≥ to 30%. **9**. Baseline Immunoglobin E (IgE) Level 30-700 IU/mL, Xolair dose – X mg SQ administration Q 4 weeks.

Q 4 Weeks	Body Weight (kg)			
IgE (IU/mL)	30-60	>60-70	>70-90	>90-150
>30-100	150	150	150	300
>100-200	300	300	300	
>200-300	300	**DO NOT DOSE**		

TOPIC	**DISCUSSION**	**DECISION/ACTION**

Xolair - Continued

Baseline IgE Level 30-700 IU/ml, Xolair dose – X mg SQ administration Q 2 weeks.

Q 2 Weeks	Body Weight (kg)			
IgE (IU/mL)	30-60	>60-70	>70-90	>90-150
>100-200				225
>200-300		225	225	300
>300-400	225	225	300	
>400-500	300	300	375	
>500-600	300	375	**DO NOT DOSE**	
>600-700	375			

10. Patient must test positive for a perennial aeroallergen AND have asthma symptoms as listed above

11. Medication needs to be shipped to the physician.

12. Physician specialty needs to be a pulmonologist, allergist, or immunologist.

After 6 months of therapy, documentation of patient's improvement must be submitted for continuation of treatment.

1. Documentation of monthly injections. If missed 2 or more injection, deny.
2. Medicaid drug profile will be run to compare with information provided.
3. Improvement in lung functions FEV1 of at least 12% of PEF of at least 20%.
4. Documentation in decrease in the number of asthma exacerbations.

TOPIC	**DISCUSSION**	**DECISION/ACTION**

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B. Actiq **Discussion of Prior Authorization Criteria**	• Dr. Schewe pointed out that this is not a prior authorization. It is a quantity limit. • Vicki stated that the beneficiary would need to have a cancer diagnosis. • Dr. Schewe asked if they would need a prior authorization form if it has to be a cancer diagnosis. • Vicki corrected herself that we will start with quantity limitation and then review the diagnosis codes that are being used.	
Public Comment	• No public comment.	
DUR Board Discussion	• Mr. Sarvis asked if the patients could get 4 units or 4 mg a day. • Vicki stated that patients could get 4 units a day. • Dr. Schewe asked if strength matters. • Dr. Whitehead stated that he thinks it would be better to leave as 4 units a day. • Dr. Waite stated that he thinks it would be better if it was a DUR limit instead of a quantity limit. • Dr. Schewe stated that it should be 4 units a day and if they exceed 4 mg a day the DUR limit will catch it.	
DUR Board Recommendation	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Mr. Sarvis and seconded by Dr. Waite to accept the SRS recommendation of Actiq quantity limit to 4 units per day. If the patient exceeds 4 units per day the DUR alert should be posted. The motion carried unanimously by roll call.

C. Heritage Interventions **DUR Board Discussion**	• Craig Boon (Heritage Information Systems) spoke about the interventions. For the antibiotic intervention, Heritage identified the high prescribers. Heritage mailed 966 letters to those high prescribers. Heritage did not get a lot of response from this, as this was an informative mailing. It did not list patient information. In mid December, Heritage mailed out 1364 letters regarding congestive heart failure. This intervention referenced patients, so Heritage received responses from many physicians. Most of the responses were positive and will be discussed in further detail in the executive session. In November, the DUR Board Members reviewed profiles regarding patients receiving 10 or more drugs per month. So far, Heritage has received a 50% response rate from prescribers. Craig stated that the next step is to decide the next quarter's intervention. Suggested interventions are Hyperlipidemia or Diabetes Mellitus Disease Management. • Vicki stated that the intervention the Board chooses would be the first quarter intervention. • Craig pointed out that Hyperlipidemia has around 8900 patients listed. He thinks this would be a very positive intervention. He also pointed out that whichever intervention they picked would probably be sent out in the next 45 days. • Dr. Lowdermik questioned whether it would be a problem that drugs that are not on the Preferred Drug List (PDL) are listed on the interventions. The Board did not see this as a problem. • Vicki stated that in the future correspondence, Heritage will highlight the Preferred Drug List drugs for education of the providers.	
TOPIC	**DISCUSSION**	**DECISION/ACTION**

Heritage - Continued **Public Comment** **DUR Board Discussion** **DUR Board Recommendation**	• Carol Curtis (AstraZeneca) asked how new drugs will be handled, since the state hasn't reviewed them yet. She also wanted to know if the manufacturers are contacted to make sure the information sent out is correct. • Craig stated that before they send out letters they make sure they have the most recent drug information. Heritage also calls manufacturers to make sure information is correct. • Dr. Schewe stated that she is in favor of doing the Hyperlipidemia intervention. • With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Bryant and seconded by Mrs. Kroger to accept Hyperlipidemia as the next intervention. The motion carried unanimously by roll call
VI. Meeting Adjournment	• There being no further discussion, a motion to adjourn was placed before the Board.	• A motion was made by Mr. Sarvis and seconded by Dr. Bryant to adjourn the meeting. The motion carried unanimously by roll call. The open meeting was adjourned at 11:00 a.m.